

**REMARKS**

Reconsideration of this application is requested.

The claims have been amended in a way which is thought to obviate the Examiner's Section 112, 1st ¶ rejection. While the applicant considers that the specification supports the "at least 5 month" recitation of claim 1 (see page 6, line 2), this language has been replaced in the amendment of claim 1 to call for continuing the administration for as long as the FMF symptoms persist. See page 5, lines 16-17 of the applicants' specification for support.

In view of the above-noted amendment of claim 1, the Examiner is requested to withdraw the Section 112, 1st ¶ rejection.

Claim 1 has also been amended in a way which is thought to emphasize the novel and unobvious aspects of the applicants' invention. Thus, the LTRA has been defined in Markush form with the active LTRA component defined either chemically or in generic fashion according to the disclosure at page 5, lines 4-10 of the applicants' specification.

The feature of claim 2 has been added to claim 1. As a consequence, claim 2 has been canceled as redundant.

Other formal changes have been made in claims 3, 5, 6 and 7 to take into account the amendment of claim 1 and the deletion of claim 2.

The Examiner is respectfully requested to reconsider the Section 103(a) rejection of claims 1-7 (now claims 1, 3-7 as unpatentable over Frenkel et al. in view of Sims et al. (U.S. Appln. 2001/0053764) and PDR (53rd edition 1999). With respect, it is submitted that the Examiner's references do not make the applicant's invention obvious. In particular, there is no suggestion, motivation or teaching in any of the references that the applicant's LTRA could be used to effectively treat FMF.

The Examiner's primary reference (Frenkel et al.), at most, only speculates that leukotriene receptor antagonists might offer a new therapeutic approach for patients with the hyperimmunoglobulinaemia D and periodic fever syndrome. The publication provides no data in support of this speculation. Even more significantly, the reference makes no mention of FMF and its treatment. The hyperimmuno-globulinaemia D and periodic fever syndrome of interest to Frenkel et al. is not the same as FMF. See, for example, the attached paper entitled "What We Treat" from the Cleveland Clinic, October 27, 2006. This paper separately discusses and distinguishes FMF from the hyperimmunoglobulinaemia D and periodic fever

syndrome (HIDS) referred to by Frenkel. Compare pages 1-2 and 4-6. Thus, Frenkel et al. only speculates as to possible treatment of a different periodic syndrome from the applicant. Taking this difference into account, along with the recognition that Frenkel et al. are only speculating as to possible use of leukotriene receptor antagonists to treat something other than FMF, it is submitted that Frenkel et al., even if considered with the Examiner's other references, cannot be suggestive of the applicant's invention or render it obvious.

It is further noted that there is nothing in Frenkel suggestive of other features of the applicant's invention, e.g. the use of the specific LTRA's called for in applicant's amended claim 1. There is also no suggestion in Frenkel et al. as to the use of oral administration as claimed.

The Examiner's secondary references do not fill in the fundamental deficiencies of Frenkel et al. Sims et al. relate to interleukin-1 inhibitors for the treatment of a variety of diseases, namely, Alzheimer's, stroke, head trauma, myocardial infarction, heart failure, acute coronary syndrome, periodontal disease, inflammatory bowel disease, asthma and pancreatitis by administration of an IL-1 receptor. See claim 1. The diseases named by Sims are not FMF or the equivalent thereof and the IL-1 receptor of Sims et al. is not an LTRA, much less one of the applicant's specific LTRA's.

The Examiner refers to Sims et al. (page 8, ¶ 0054) as showing that periodic fever syndrome includes FMF. This paragraph of Sims et al. reads:

"Also treatable with the compounds, compositions and combination therapies of the invention are inherited periodic fever syndromes, including familial Mediterranean fever, hyperimmunoglobulin D and periodic fever syndrome and TNF-receptor associated periodic syndromes (TRAPS)."

The Examiner's reference to the Sims et al. disclosure of FMF as "periodic fever syndrome" suggests that she may have misinterpreted the Frenkel et al. disclosures of hyperimmunoglobulinaemia D and periodic fever syndrome. Thus, Frenkel et al. do not refer to periodic fever syndromes generally but in fact, refer specifically to hyperimmunoglobulinaemia D and periodic fever syndrome, i.e. HIDS. This is specifically different from FMF.

The Sims et al. disclosure admittedly identifies FMF as an inherited periodic fever syndrome. However, as noted, Frenkel et al. refer specifically to one type of

periodic fever syndrome (HIDS) which is different from the FMF of concern to the applicant. In fact, the Sims et al. disclosure really supports the applicant's position in that it recognizes that the problem of interest to the applicant is different from the "hyperimmunoglobulinaemia D and periodic fever syndrome" referred to by Frenkel et al. These are both inherited periodic fever syndromes, as is TRAPS (also referred to by Sims et al.). However, each is different as shown by the Cleveland Clinic paper attached hereto. Thus, even if Frenkel et al. and Sims et al. are considered together, when there is no reason to do so apart from reconstructive hindsight on the basis of the applicant's teaching, the applicant's invention does not result because there is clearly nothing in the references to suggest singling out the FMF referred to by Sims et al. for treatment with an LTRA. This is particularly so in the absence of any reference in Frenkel et al. or Sims et al. to the possibility of using any LTRA to treat FMF, much less the specific LTAs called for by amended claim 1.

The Examiner's PDR reference does not fill in the fundamental deficiencies of the Examiner's other references. The applicant acknowledges that his LTAs are known *per se* for other therapeutic uses. However, there is no suggestion in the PDR that the applicant's LTAs could be used to treat FMF. This is also true for Frenkel et al. and Sims et al. Accordingly, it is respectfully submitted that the Examiner's Section 103(a) rejection should be withdrawn and the claims, as amended, allowed.

Favorable action is requested.

Respectfully submitted,



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